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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,876	11/18/2000	John E. Edwards JR.	259/064	7636

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 06/18/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/715,876

Applicant

Edwards et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 9, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, and 9 ~~is/are~~ pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, and 9 ~~is/are~~ rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Serial Number: 09/715,876
Art Unit: 1645

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 04/09/03 (paper no. 13) in response to the non-final Office Action mailed 10/09/02 (paper no. 11).

Status of Claims

- 2) Claims 2 and 4 have been canceled via the amendment filed 04/09/03.
Claims 1 and 3 have been amended via the amendment filed 04/09/03.
New claim 9 has been added via the amendment filed 04/09/03.
Claims 1, 3 and 9 are pending and are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Specification - Informality

- 5) The specification introduced to page 10, line 6 of the specification via the amendment filed 04/09/03 (paper no. 13) is confusing. The sentence states:

Figure 7 is the polynucleotide (SEQ ID NO: 7) polypeptide sequence of Als1p (SEQ ID NO: 8).

It is unclear how SEQ ID NO: 7 can represent both a polynucleotide and a polynucleotide. It is noted that the raw Sequence Listing filed 04/09/03 identified SEQ ID NO: 7 to be a DNA sequence, but not an amino acid sequence. It is further confusing that the new claim 9 identifies SEQ ID NO: 7 to be a protein.

Objection(s) Withdrawn

- 6) The objection to the specification made in paragraph 7(b) of the Office Action mailed 04/09/03 (paper no. 11) is withdrawn in light of Applicants' amendment to the specification.
7) The objection to claim 1 made in paragraph 15(a) of the Office Action mailed 04/09/03 (paper no. 11) is withdrawn in light of Applicants' amendment to the specification.

Serial Number: 09/715,876
Art Unit: 1645

Objection(s) Maintained

- 8) The objection to the drawing made in paragraph 5 of the Office Action mailed 04/09/03 (paper no. 11) is maintained for reasons set forth therein. Applicants have assured the Office that they would submit the required formal drawings upon the receipt of the Notice of Allowability.

Objection(s) Moot

- 9) The objection to claim 4 made in paragraph 15(b) of the Office Action mailed 04/09/03 (paper no. 11) is moot in light of Applicants' cancellation of the claim.

Objection(s) Withdrawn

- 10) The objection to the specification made in paragraph 7(a) of the Office Action mailed 04/09/03 (paper no. 11) is withdrawn in light of Applicants' amendments to the specification.

Rejection(s) Moot

- 11) The rejection of claims 2 and 4 made in paragraph 8 of the Office Action mailed 04/09/03 (paper no. 11) under 35 U.S.C § 112, first paragraph, as containing inadequate written description, is moot in light of Applicants' cancellation of the claims.
- 12) The rejection of claim 4 made in paragraph 10(a) of the Office Action mailed 04/09/03 (paper no. 11) under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.
- 13) The rejection of claim 2 made in paragraph 10(c) of the Office Action mailed 04/09/03 (paper no. 11) under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.
- 14) The rejection of claim 2 made in paragraph 12 of the Office Action mailed 04/09/03 (paper no. 11) under 35 U.S.C. § 102(b) as being anticipated by Hoyer *et al.* (*J. Bacteriol.* 180: 5334-5343, October 1998) (Hoyer *et al.*, 1998), is moot in light of Applicants' cancellation of the claim.
- 15) The rejection of claim 2 made in paragraph 14 of the Office Action mailed 04/09/03 (paper no. 11) under 35 U.S.C. § § 103(a) as being unpatentable over Hoyer *et al.* (*Mol. Microbiol.* 15: 39-54, 1995 - Applicants' IDS) (Hoyer *et al.*, 1995), is moot in light of Applicants' cancellation of the claim.

Rejection(s) Withdrawn

- 16) The rejection of claim 3 made in paragraph 10(b) of the Office Action mailed 04/09/03 (paper

Serial Number: 09/715,876
Art Unit: 1645

no. 11) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

17) The rejection of claim 1 made in paragraph 10(d) of the Office Action mailed 04/09/03 (paper no. 11) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

18) The rejection of claims 1 and 3 made in paragraph 8 of the Office Action mailed 04/09/03 (paper no. 11) under 35 U.S.C § 112, first paragraph, as containing inadequate written description, is maintained for reasons set forth therein and herebelow.

Applicants state that the amendment to claim 1 traverses the pending written description issue. No specific arguments have been advanced.

Applicants' statement has been carefully considered, but is non-persuasive. The amendment made to claim 1 does not obviate a part of the rejection explained in the last half of paragraph 8 of the Office Action mailed 04/09/03 (paper no. 11). ALS1 is described in the art to differ across strains and in some cases, even between ALS1 alleles in the same strain, thus suggesting a strain-dependent variability. See the paragraph bridging left and right columns on page 39 of Hoyer *et al.* (*Mol. Microbiol.* 15: 39-54, January 1995 - Applicants' IDS). ASL1 differed between two strains, for example, strains SB B311 and B792. See last paragraph in right column on page 42 of Hoyer *et al.* The disclosed structural feature for one ASL1 species (strain) does not constitute adequate description of the claimed broad asl1P genus. Therefore, the disclosure of a single ASL1 sequence from a single strain of *Candida albicans* does not provide an adequate description of the claimed genus of cell surface adhesin protein from any *Candida albicans* strain, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicants were in possession of the genus of cell surface adhesin proteins as claimed. See Written Description Requirement published in *Federal Register*, Vol. 66, No. 4, Friday, 05 January 2001, Notices, p. 1099-1111. The rejection stands.

19) The rejection of claims 1 and 3 made in paragraph 12 of the Office Action mailed 04/09/03 (paper no. 11) under 35 U.S.C. § 102(b) as being anticipated by Hoyer *et al.* (*J. Bacteriol.* 180: 5334-5343, October 1998) (Hoyer *et al.*, 1998), is maintained for reasons set forth therein and

Serial Number: 09/715,876
Art Unit: 1645

herebelow.

20) The rejection of claims 1 and 3 made in paragraph 14 of the Office Action mailed 04/09/03 (paper no. 11) under 35 U.S.C. § 103(a) as being unpatentable over Hoyer *et al.* (*Mol. Microbiol.* 15: 39-54, 1995 - Applicants' IDS) (Hoyer *et al.*, 1995), is maintained for reasons set forth therein and herebelow.

Applicants contend that the amended claims specify that the pharmaceutical composition is useful as a vaccine to promote an immune response against the als1P protein. Applicants submit that there is no meaningful disclosure in the Hoyer (1998) reference of the formulation of an als1P protein to yield an effective result as a vaccine. Applicants state that the amended claim language distinguishes the Hoyer (1998) reference by requiring that the claimed pharmaceutical composition has the operative property of yielding a protective immune response.

With regard to the rejection under 35 U.S.C. § 103(a), Applicants cite parts of Hoyer's (1995) teaching and assert that Hoyer *et al.* (1995) do not disclose any useful immunological function for the als1P protein and do not make the leap from speculating that the alsP1 protein has a potential role in adhesin. Applicants state that the reference does not disclose a formulation that has been demonstrated to yield any immune response or the protective immune response. Applicants submit that under 35 U.S.C. § 103 the cited prior art references must be considered 'as a whole' and must suggest the desirability and the obviousness of making the invention. Applicants cite case law and allege that an obviousness rejection cannot be based on the proposition that one of ordinary skill in the art would have been motivated to engage in an open-ended exercise to try all manner of experiments until one possible variation reaches an Applicants' claimed invention.

Applicants' arguments have been carefully considered, but are non-persuasive. The cited reference has been considered as a whole. As set forth previously, the term 'vaccine' in the claims, or the alleged 'usefulness' of a product represents the intended use and has no patentable weight. Instant claims, as currently drafted, do not define the claimed protein or the N-terminal fragment structurally. The claimed protein or the N-terminal fragment protein does not exclude Hoyer's protein (1998 or 1995). Since the claimed protein or the N-terminal fragment protein is not identified by one or more structural limitations, it encompasses Hoyer's or any other isolated and purified protein or the N-terminal fragment protein of *Candida albicans*. The base claim 1, as

Serial Number: 09/715,876
Art Unit: 1645

amended, includes a functional limitation without reciting sufficient structure. In the instant case, the only structural limitation that needs to be met by a prior art isolated and purified protein is that it must be of *Candida albicans* origin. The functional limitation, on which the prior art reference is allegedly silent, is considered as an inherent property inseparable from the prior art protein. It is well known in the art that a microbial adhesin protein would intrinsically elicit an anti-adhesin immune response since proteins are well recognized in the art as good immunogens. Where the only difference between the claimed product and the prior art product is recited in the functional language, i.e., by what it does rather than what it is, it is incumbent upon Applicants, when challenged by the USPTO, to demonstrate that the prior art product does not actually possess those characteristics. The term 'vaccine' represents the intended use of the product and has no patentable weight. The rejections stand.

New Rejection(s)

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments to the claims and/or the submission of a new claim.

Rejections under 35 U.S.C. § 112, Second Paragraph

21) Claims 1, 3 and 9 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is vague and/or incorrect in the recitation "aggluttin" (see line 2), because it is unclear what is encompassed in this limitation. The specification does not describe or define any 'aggluttin'.

(b) Claim 1 is vague and/or incorrect in the recitation "block adhesin of *Candida albicans* to endothelial cells" (see line 4), because it is unclear what is encompassed in the limitation 'adhesin'. Is 'adhesin' a functional limitation, or does it represent the potential 'adhesin' protein of *Candida albicans*, or is this limitation meant to be 'adhesion'?

(c) Claim 3 is vague in the recitation "the protein is an N-terminal fragment", because the origin or the source of the recited 'an N-terminal fragment' is unclear. The claimed protein encompasses a protein which can comprise its own homologous N-terminal fragment, or an N-

Serial Number: 09/715,876

Art Unit: 1645

terminal fragment of a heterologous protein. Is this the N-terminal fragment of the als1 cell surface adhesin protein recited in claim 1, or is it any random N-terminal fragment of any unknown protein other than the als1 cell surface adhesin protein recited in claim 1? The same criticism applies as to the source of the recited 'the adhesin binding site', because it is unclear whether this site is the adhesin binding site of the protein claimed in claim 1, or of a heterologous protein.

(d) Claim 9 is indefinite, confusing and/or incorrect in the recitation: "SEQ ID NO: 7", without specifying that the recited SEQ ID number represents an amino acid or nucleotide sequence. Furthermore, the recitation 'the protein is SEQ ID NO: 7' is inconsistent with the information provided in the raw Sequence Listing, because the Sequence Listing identifies 'SEQ ID NO: 7' to be a DNA sequence. It is not clear whether the vaccine claimed in claim 9 comprises a protein or a polynucleotide.

Remarks

22) Claims 1, 3 and 9 stand rejected.

23) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

24) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for

Serial Number: 09/715,876
Art Unit: 1645


submission of after-final amendments is (703) 872-9307.

25) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER